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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,162	08/29/2006	Kornelia Polyak	00530-116USI DFCI 853.02	5286
26161 7590 03/26/2009 FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022				
EXAMINER SITTON, JEHANNE SOUAYA				
ART UNIT		PAPER NUMBER		
1634				
NOTIFICATION DATE		DELIVERY MODE		
03/26/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary

Application No.

10/550,162

Applicant(s)

POLYAK ET AL.

Examiner

Jehanne S. Sitton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 29 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 8-23, 26, 32, 40, 50, 51, 58, 64, 71-74 and 77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1, 2, 8-23, 26, 32, 40, 50, 51, 58, 64, 71-74, 77 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Groups 1, claim(s) 1, in part, drawn to a method of diagnosis by determining the level of expression of a gene in Table 1. This group is subject to further restriction.

Group 2, claim 2, in part, drawn to a method of DCIS by determining the level of expression of 10 or more genes from tables 2-16. This group is subject to further restriction.

Groups 3, claim(s) 8 in part, drawn to a method of determining the likelihood that a breast cancer is invasive by determining the level of expression of one of 7 different genes listed in claim 8. This group is subject to further restriction.

Groups 4, claim(s) 9, in part, drawn to a method of predicting the prognosis of a breast cancer by determining the level of expression of a gene encoding S100A7 or FASN. This group is subject to further restriction.

Group 5, claim(s) 10-21, in part, drawn to a method of diagnosis by determining expression of a gene from Tables 7, 8, 10, 15, or 16. This group is subject to further restriction.

Group 6, claim(s) 22, in part, drawn to a method of diagnosis by determining expression of a gene from tables 9 or 15, which is elevated as compared to normal cells. This group is subject to further restriction.

Group 7, claim(s) 23, in part, drawn to a method of diagnosis by determining expression of a gene from tables 9 or 15 which is decreased as compared to normal cells. This group is subject to further restriction.

Group 8, claim(s) 26, in part, drawn to a method of inhibiting proliferation of a breast cell by contacting with a polypeptide encoded by a gene in tables 1, 7-10, or 15. This group is subject to further restriction.

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Group 9, claim(s) 32, in part, drawn to a method of inhibiting pathogenesis of a cancer cell in a tumor by in vivo methods of treatment with an agent that inhibits binding of a polypeptide to its receptor, wherein the polypeptide is encoded by a gene in tables 2-10, 15, or 16. This group is subject to further restriction.

Group 10, claim(s) 40, in part, drawn to a method of inhibiting gene expression of a gene in tables 2-10, 15 or 16 using antisense. This group is subject to further restriction.

Group 11, claim(s) 50 and 73-74, in part, drawn to a nucleic acid probe comprising a tag selected from a tag in tables 1-5, 7-10, 15, or 16 or figure 7. This group is subject to further restriction.

Group 12, claim(s) 51 and 58, in part, drawn to an array and kit comprising at least 10 probes comprising a tag from tables 1-10, 15, or 16. This group is subject to further restriction.

Group 13, claim(s) 64, in part, drawn to at least 10 antibodies specific for a protein encoded by a gene listed in tables 1-5, 7-10, 15, or 16. This group is subject to further restriction.

Group 14, claim(s) 71, drawn to a method of identifying the grade of DCIS by using an array of claim 51. This group is subject to further restriction.

Group 15, claim(s) 72, drawn to a method of determining whether a breast cancer is DCIS or an invasive breast cancer by determining the level of expression of CXCL14 in myofibroblasts.

Group 16, claim(s) 77, drawn to a polypeptide encoded by a DNA of claim 73. This group is subject to further restriction.

2. Further Restriction applicable to groups 1-14 and 16. The claims recite numerous gene/sequences in the alternative, either as a single or a combination of genes/sequences from the tables listed in the claims. Depending on which group is elected, applicant is required to elect a single gene or sequence or a single combination of genes or sequences as set forth in each claim listed above, to which the claims will be limited. This is not an election of species. Each gene/sequence is structurally and functionally distinct.

3. The inventions listed as Groups 1-15 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The claims are directed to methods of using as well as products directed to structurally and functionally distinct genes/sequences. These sequences therefore lack the same or corresponding special technical feature. Additionally, each group is drawn to different structurally and functionally different products (nucleic acids, polypeptides) and different methods using different steps or methods of operation. As such, the groups further lack the same or corresponding special technical feature. Accordingly, the claims lack unity of invention.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102,

103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoiner in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoiner.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sittton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday, Tuesday and Thursday from 9:00 AM to 3:00 PM.

NOTE: The examiner will be on Maternity Leave April to August 2009.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and

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history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Jehanne Sitton/
Primary Examiner
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